

Attorney Docket Number: MBIO1999-057CP2RCEM Serial Number: 09/503,387

REMARKS

Claims 26-29, 33-47, 53, 54, 65-79 and 87-90 were pending in this application as of the Office Action dated July 21, 2005.

Applicants have amended claims 26, 27, 29, 33, 34, 36, 37-39, 41-43, 45-46, 53-54, 65 and 69-79 in an effort to obviate the Examiner's 35 U.S.C. § 112, second paragraph rejections, as discussed below. Claims 26-29, 33-47, 53, 54, 65-79, and 87-90 will therefore be pending upon entry of this Amendment. The amendments and remarks made herein are designed to place the case in condition for allowance. As such, Applicants respectfully request that the amendments and remarks made herein be entered and fully considered.

Rejection of Claims 26-29, 33-34, 36-39, 41-43, 45-46, 53-54, 65 and 69-79

Under 35 U.S.C. § 112, ¶2

Claims 26-29, 33-34, 36-39, 41-43, 45-46, 53-54, 65 and 69-79 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

The Examiner has rejected claims 26, 27, 29, 33, 34, 71, 74, 78 and 79 under 35 U.S.C. § 112, second paragraph, because "[i]t is not clear if the polypeptide...to which the claimed antibody or fragment binds is open or close ended". The Examiner has suggested the incorporation of the term "comprising" in these claims. Applicants have amended claims 26, 27, 29, 33, 34, 71, 74, 78 and 79 to recite the term "comprising" as suggested by the Examiner, thereby rendering the U.S.C. § 112, second paragraph rejection over claims 26, 27, 29, 33, 34, 71, 74, 78 and 79 moot.

The Examiner has additionally rejected claim 28 under 35 U.S.C. § 112, second paragraph, stating that there is no antecedent basis in base claim 27 for the term "humanized antibody" recited in claim 28. The Examiner has suggested that claim 27 be amended to read "A substantially purified non-human monoclonal antibody or humanized antibody or fragment thereof..." in order to provide antecedent basis for claim 28. Applicants respectfully disagree

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with the Examiner's proposal as one of skill in the art would recognize that a non-human monoclonal antibody can be humanized in order to make it less immunogenic. There is no antecedent basis problem with claim 28 as it recites "The antibody of claim 27" and then further characterizes that antibody as being a humanized antibody. Applicants therefore respectfully request reconsideration and withdrawal of the U.S.C. § 112, second paragraph rejection over claim 28.

The Examiner additionally rejected claims 33 and 34 under 35 U.S.C. § 112, second paragraph, stating that the term "antibody is conjugated to a therapeutic moiety / detectable substance" is indefinite and ambiguous because the preamble recites an antibody or fragment thereof and not a conjugated antibody. The Examiner suggests the incorporation of the term "conjugated" in the preamble of claims 33 and 34. Applicants respectfully disagree with the Examiner. Applicants assert that claims 33 and 34 are not indefinite or ambiguous and that there is no need to add the term "conjugated" in the preamble of these claims. The claims recite an antibody, which is then further defined using the transitional term "wherein", which serves to further characterize the antibody as being conjugated to either a therapeutic moiety or a detectable substance. Addition of the term "conjugated" within the preamble would simply render the claims confusing. Therefore, Applicants respectfully request reconsideration and withdrawal of the 35 U.S.C. § 112, second paragraph rejection over claims 33 and 34.

The Examiner additionally rejected claim 36 under 35 U.S.C. § 112, second paragraph as being indefinite and ambiguous because "[i]t is not clear what is the relationship between TANGO268 polypeptide and polypeptide of SEQ ID NO:3". The Examiner suggested removing the portion of the claim which recited the TANGO268 polypeptide, however Applicants disagree with the Examiner's proposal. Rather, Applicants have amended claim 36 to refer to the SEQ ID NO which contains the TANGO268 polypeptide sequence. Claim 36 therefore reads "A substantially purified antibody or a fragment thereof which specifically binds to *the* extracellular domain of the amino acid sequence of SEQ ID NO:3, wherein said antibody or fragment *thereof* does not contain more than 30% of contaminating antibodies directed against epitopes other than those on the *amino acid sequence of SEQ ID NO:3*." Applicants submit that the proposed

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amendment overcomes the Examiner's rejection and respectfully request reconsideration and withdrawal of the 35 U.S.C. § 112, second paragraph rejection over claim 36.

The Examiner also rejected claim 37 under 35 U.S.C. § 112, second paragraph as being indefinite and ambiguous because of the term "about". Applicants have deleted the term "about" from claim 37 as suggested by the Examiner, thereby rendering the rejection moot.

The Examiner also rejected claim 38 under 35 U.S.C. § 112, second paragraph as being indefinite and ambiguous because of the term "comprises". Applicants have replaced the term "comprises" with the term "consists of" as suggested by the Examiner, thereby rendering the rejection moot.

The Examiner also rejected claim 39 under 35 U.S.C. § 112, second paragraph as being indefinite and ambiguous because of the term "about". Applicants have deleted the term "about" from claim 39 as suggested by the Examiner, thereby rendering the rejection moot.

The Examiner also rejected claims 41-43 under 35 U.S.C. § 112, second paragraph as being indefinite because of the term "an". Applicants have replaced the term "an" with the term "the" in claims 41-43 as suggested by the Examiner, thereby rendering the rejection moot.

The Examiner additionally rejected claims 45 and 46 under 35 U.S.C. § 112, second paragraph, stating that the term "conjugated" needs to be added to the preamble of the claims. Applicants respectfully traverse this rejection and state that there is no need to add the term "conjugated" in the preamble of claims 45 and 46. Claim 36, from which claims 45 and 46 depend, recites a substantially purified antibody or fragment thereof which is un-conjugated. Claims 45 and 46 depend on claim 36 and further limit the scope of claim 36 by stating "wherein the antibody is conjugated". Addition of the term "conjugated" within the preamble of claims 45 and 46 would render the claims confusing and would introduce clarity issues. Therefore, Applicants respectfully request reconsideration and withdrawal of the 35 U.S.C. § 112, second paragraph rejection over claims 45 and 46.

The Examiner also rejected claims 53-54 under 35 U.S.C. § 112, second paragraph, as being indefinite because of the term "an". Applicants have replaced the term "an" with the term "the" in claims 53-54 as suggested by the Examiner, thereby rendering the rejection moot.

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The Examiner also rejected claim 65 under 35 U.S.C. § 112, second paragraph as being indefinite and ambiguous because of the term "GPVT". Applicants have amended claim 65 as suggested by the Examiner, thereby rendering the rejection moot.

The Examiner also rejected claim 69 under 35 U.S.C. § 112, second paragraph as being indefinite because of the term "recognize". Applicants have replaced the term "recognize" with the term "binds to" in claim 69 as suggested by the Examiner, thereby rendering the rejection moot.

The Examiner also rejected claim 70 under 35 U.S.C. § 112, second paragraph as being indefinite because of the term "an". Applicants have replaced the term "an" with the term "the" in claim 70 as suggested by the Examiner, thereby rendering the rejection moot.

The Examiner also rejected claim 71 under 35 U.S.C. § 112, second paragraph as being indefinite and ambiguous "[b]ecause it is not clear how monoclonal antibody in the preamble becomes a human antibody, humanized antibody or chimeric antibody." The Examiner suggests amending claim 71 to read "An antibody or fragment thereof which specifically binds to a polypeptide comprising the amino acid sequence of SEQ ID NO:3, or the amino acid sequence encoded by the cDNA insert of the plasmid deposited with ATCC as Accession Number 207180 wherein the antibody is a monoclonal antibody, a human antibody, a humanized antibody or a chimeric antibody." Applicants respectfully traverse this rejection. Applicants submit that there are no clarity issues with claim 71 as one of skill in the art would recognize that a monoclonal antibody can be a human monoclonal antibody, a humanized monoclonal antibody or a chimeric monoclonal antibody. The Examiner's suggestion would therefore unnecessarily change the scope of the claim. In order to address the issue, Applicants have amended the claim to read "A monoclonal antibody or fragment thereof which specifically binds to a polypeptide *comprising* the amino acid sequence of SEQ ID NO:3, or the amino acid sequence encoded by the cDNA insert of the plasmid deposited with the ATCC as Accession Number 207180, wherein the *monoclonal* antibody is a human *antibody*, a humanized *antibody* or a chimeric *antibody*". Therefore, Applicants respectfully request reconsideration and withdrawal of the 35 U.S.C. § 112, second paragraph rejection over claim 71.

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The Examiner additionally rejected claims 72 and 73 under 35 U.S.C. § 112, second paragraph, stating that the term “conjugated” needs to be added to the preamble of the claims. Applicants respectfully traverse this rejection and state that there is no need to add the term “conjugated” in the preamble of the claims. Claim 71, from which claims 72 and 73 depend, recites a monoclonal antibody or fragment thereof which is un-conjugated. Claims 72 and 73 depend on claim 71 and further limit the scope of claim 71 by stating “wherein the antibody is conjugated”. Addition of the term “conjugated” within the preamble of claims 72 and 73 would render these claims confusing and would introduce clarity issues. Therefore, Applicants respectfully request reconsideration and withdrawal of the 35 U.S.C. § 112, second paragraph rejection over claims 72 and 73.

The Examiner also rejected claim 74 under 35 U.S.C. § 112, second paragraph as being indefinite and ambiguous “[b]ecause it is not clear how monoclonal antibody in the preamble becomes a human antibody, humanized antibody or chimeric antibody at the end linked to a detectable substance”. The Examiner suggests amending claim 74 to read “A conjugated antibody or fragment thereof wherein the antibody is linked to a detectable substance selected from the group consisting of an enzyme, a prosthetic group, a fluorescent material, a luminescent material, a bioluminescent material, and a radioactive material, and specifically binds to a polypeptide comprising the amino acid sequence of SEQ ID NO:3, or the amino acid sequence encoded by the cDNA insert of the plasmid deposited with the ATCC as Accession Number 207180 and wherein the antibody is a monoclonal antibody, a human antibody, a humanized antibody or a chimeric antibody.” Applicants respectfully traverse this rejection. Applicants submit that there are no clarity issues with claim 74 as one of skill in the art would recognize that a monoclonal antibody can be a human monoclonal antibody, a humanized monoclonal antibody or a chimeric monoclonal antibody and that a human monoclonal antibody, a humanized monoclonal antibody or a chimeric monoclonal antibody can be conjugated to a detectable substance. The Examiner’s suggestion would therefore unnecessarily change the scope of the claim. Additionally, Applicants feel it unnecessary to incorporate the term “conjugated” in the preamble of claim 74. The claim recites “A monoclonal antibody or fragment thereof which is conjugated...”. Addition of the term “conjugated” within the preamble would simply render the

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claim confusing and redundant. In order to address the Examiner's issues, Applicants have amended the claim to read "A monoclonal antibody or fragment thereof which is *conjugated* to a detectable substance selected from the group consisting of an enzyme, a prosthetic group, a fluorescent material, a luminescent material, a bioluminescent material, and a radioactive material, and which specifically binds to:

- a) a polypeptide *comprising* the amino acid sequence of SEQ ID NO:3; or
- b) the amino acid sequence encoded by the cDNA insert of the plasmid deposited with the ATCC as Accession Number 207180,

wherein the *monoclonal* antibody is a human *antibody*, a humanized *antibody* or a chimeric antibody."

Therefore, Applicants respectfully request reconsideration and withdrawal of the 35 U.S.C. § 112, second paragraph rejection over claim 74.

The Examiner also rejected claims 75-77 under 35 U.S.C. § 112, second paragraph, as being indefinite because of the term "an". Applicants have replaced the term "an" with the term "the" in claims 75-77 as suggested by the Examiner, thereby rendering the rejection moot.

The Examiner also rejected claim 78 under 35 U.S.C. § 112, second paragraph as being indefinite and ambiguous "[b]ecause it is not clear how a kit comprising monoclonal antibody in the preamble becomes a kit comprising human antibody, humanized antibody or chimeric antibody". The Examiner suggests amending claim 78 to read "A kit comprising an antibody or fragment thereof which specifically binds to a polypeptide comprising the amino acid sequence of SEQ ID NO:3, or the amino acid sequence encoded by the cDNA insert of the plasmid deposited with ATCC as Accession Number 207180 wherein the antibody is a monoclonal antibody, a human antibody, a humanized antibody or a chimeric antibody, and instructions for use." Applicants respectfully traverse this rejection. Applicants submit that there are no clarity issues with claim 78 as one of skill in the art would recognize that a monoclonal antibody can be a human monoclonal antibody, a humanized monoclonal antibody or a chimeric monoclonal antibody. The Examiner's suggestion would unnecessarily change the scope of the claim. In order to address the issue, Applicants have amended the claim to read "A kit comprising a monoclonal antibody or fragment thereof which specifically binds to a polypeptide *comprising*

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the amino acid sequence of SEQ ID NO:3, or the amino acid sequence encoded by the cDNA insert of the plasmid deposited with the ATCC as Accession Number 207180, wherein the *monoclonal* antibody is a human *antibody*, a humanized *antibody* or a chimeric antibody, and instructions for use.” Therefore, Applicants respectfully request reconsideration and withdrawal of the 35 U.S.C. § 112, second paragraph rejection over claim 78.

The Examiner also rejected claim 79 under 35 U.S.C. § 112, second paragraph as being indefinite and ambiguous “[b]ecause it is not clear how a kit comprising monoclonal antibody linked to a detectable substance in the preamble becomes a kit comprising human antibody, humanized antibody or chimeric antibody at the end linked to a detectable substance”. The Examiner suggests amending claim 79 to read “A kit comprising a conjugated antibody or fragment thereof which is linked to a detectable substance, and which specifically binds to a) a polypeptide comprising the amino acid sequence of SEQ ID NO:3, or b) the amino acid sequence encoded by the cDNA insert of the plasmid deposited with ATCC as Accession Number 207180 wherein the antibody is a monoclonal antibody, a human antibody, a humanized antibody or a chimeric antibody, and instructions for use.” Applicants respectfully traverse this rejection. Applicants submit that there are no clarity issues with claim 79 as one of skill in the art would recognize that a monoclonal antibody can be a human monoclonal antibody, a humanized monoclonal antibody or a chimeric monoclonal antibody and that a human monoclonal antibody, a humanized monoclonal antibody or a chimeric monoclonal antibody can be conjugated to a detectable substance. The Examiner’s suggestion would unnecessarily change the scope of the claim. Additionally, Applicants feel it unnecessary to incorporate the term “conjugated” in the preamble of claim 79. The claim recites “A kit comprising a monoclonal antibody or fragment thereof which is conjugated...”. Addition of the term “conjugated” within the preamble would simply render the claim confusing and redundant. In order to address the issue, Applicants have amended the claim to read “A kit comprising a monoclonal antibody or fragment thereof which is *conjugated* to a detectable substance, and which specifically binds to:

- a) a polypeptide *comprising* the amino acid sequence of SEQ ID NO:3; or
- b) the amino acid sequence encoded by the cDNA insert of the plasmid deposited with the ATCC as Accession Number 207180,

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wherein the *monoclonal* antibody is a human *antibody*, a humanized *antibody* or a chimeric antibody, and instructions for use.”

Therefore, Applicants respectfully request reconsideration and withdrawal of the 35 U.S.C. § 112, second paragraph rejection over claim 79.

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In view of the amendments and remarks made herein, Applicants respectfully submit that the rejections presented by the Examiner are now overcome and that this application is in condition for allowance. If in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject application, the Examiner is invited to call the undersigned.

This paper is being filed timely as no extensions of time are required. In the event any extensions of time are necessary, the undersigned hereby authorizes the requisite fees to be charged to Deposit Account No. 501668.

Entry of the remarks made herein is respectfully requested.

Respectfully submitted,

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